

REMARKS/ARGUMENTS

This Submission is made under the Rule of 1.116. The admission of this Submission and reconsideration of the present application are respectfully requested.

A. Status of the Claims

Claims 1-24 are presented for further prosecution. No amendment is made in this submission.

B. Claims Rejections under 35 U.S.C. § 103(a)

The Examiner made several rejections under 35 U.S.C. § 103(a). In order to maintain an obviousness rejection under 35 U.S.C. § 103(a), the differences between the claimed invention and prior art must be obvious to a person of ordinary skill in the art at the time the claim invention was made. As will be shown below, Applicants respectfully submit that the differences between the claimed invention and the combination of the teachings of cited art are not obvious as required to maintain an obviousness rejection under 35 U.S.C. § 103(a).

1. Claims Rejections based on Nellhaus in view of Verschuur

The Examiner rejected the subject matter of claims 1, 3, 4, 6-8, 11-18, 20 and 21 as being unpatentable over Nellhaus in view of Verschuur. Applicants note the Examiner recognized that Nellhaus does not teach covert markings and cited Verschuur for the markings being invisible.

The present invention relates to an oral solid dosage form, i.e. a tablet, having a core portion having sufficiently low friability to receive a printed or etched marking on a surface and a covert readable printed or etched marking on the surface of the core. It further relates to a method of applying a readable printed or etched covert marking which provides identification/authentication criteria on the surface an oral solid dosage form.

However, Verschuur does not teach a covert marking on the surface of an oral solid dosage

form. Instead, Verschuur directs to a completely unrelated technology, in which the contents of sealed envelopes are detected. According to Verschuur, this is carried out by testing and digitizing a change in capacitance produced by dielectric or conductive ink printed as a bar-code on envelopes (see column 2, lines 53-61 of Verschuur). It is clear that Verschuur is in a different technology from the present invention. Verschuur has nothing to do with pharmaceutical tablets. There is absolutely no guidance to be gleaned from the reference for marking an oral solid dosage form.

The Examiner cites the following paragraph in Verschuur:

"The *conductive ink* used for printing the bar-code 12 can be visible for conveying additional optically readable information on the inserts 11 or can be invisible for performing other functions such as those relating to tracking, accounting, or security. The bar-code 12 can also be hidden between layers of the inserts 11 for similar purposes." (Column 4, lines 50-55).

Applicants wish to point out that Verschuur's invisible marks are made with invisible conductive ink, and the conductivity of this conductive ink is critical in Verschuur's contents detection. However, the use of conductive ink and the detecting and digitizing a change in capacitance produced by the conductive ink are not acceptable in pharmaceutical products. Verschuur's use of conductive ink destroys any motivation to apply its teachings to Nellhaus. Therefore, one seeking to make an oral solid dosage form would not look to the Verschuur patent.

It is respectfully submitted that the teachings of Verschuur can not be properly combined with Nellhaus and the disclosure of Nellhaus in view of Verschuur does not teach or suggest an oral solid dosage form with covert markings for identification.

2. Claim Rejections based on Nellhaus in view of Verschuur and Sullivan

The Examiner rejected the subject matter of claims 2, 5, 19, 23 and 24 as being unpatentable over Nellhaus in view of Verschuur and Sullivan.

As discussed in item 1 of this section, Verschuur can not be combined with Nellhaus and it

does not teach a covert mark for an oral solid dosage form. This fatal deficiency is not remedied by the teaching of Sullivan.

Sullivan describes the use of micro bar codes, which are visible to the eye, even though they might not be capable of being interpreted without a scanner or similar device. For example, Sullivan teaches “[A] bar-type code may be either printed directly on an outer surface of the pill, on another layer located beneath the outer layer of the pill yet visible from the exterior of the pill, or printed on a label that is secured to any outer surface layer or underlying layer of the pill” (see column 5, lines 5-10, Sullivan). It is clear that the Sullivan teaches visible markings, not covert/invisible markings. Therefore the combination of Nellhaus, Verschuur and Sullivan does not make claims 2, 5, 19, 23 and 24 obvious.

3. Claim Rejections based on Nellhaus in view of Verschuur and Johnson

The Examiner further rejected the subject matter of claims 9 and 10 as being unpatentable over Nellhaus in view of Verschuur and Johnson.

Johnson teaches a “taste-masking layer” to coat the substrate core (see column 12, lines 65-67, as cited by the Examiner). However, this taste-masking layer is not the same as the tastable markings recited in Claim 9, and the taste-masking layer is certainly not covert. Therefore, Johnson does not teach or suggest a covert marking that is detectable by taste. Therefore the combination of Nellhaus, Verschuur and Johnson does not make claims 9 and 10 obvious.

4. Claim Rejections based on Nellhaus in view of Verschuur and Krubert

The Examiner further rejected the subject matter of claim 22 as being unpatentable over Nellhaus in view of Verschuur and Krubert.

Krubert mentions that a suitable yellow ink on printed food products can be Opaque ink. However, Krubert does not disclose any covert marking printed on the food or baked product. Krubert uses a 4-head pan flex printer, which is designed to print visible images on the product. It

can be seen that, in the figures 3, 3A, 4, 4A, 5 and 5A, all the printed marks are visible or intended to be visible to the customers. Thus, the combination of Nellhaus, Verschuur and Krubert does not teach or suggest the method of applying cover markings on dosage forms as in the dependent claim 22.

In summary, no teaching or suggestion of a covert marking on oral dosage forms has been given in any of the cited references stand alone or in combination. The differences between the claimed invention and the combined teachings of Nellhaus, Verschuur, Sullivan, Johnson and/or Krubert are not obvious to a person of ordinary skill in the art, as required to maintain an obviousness rejection under 35 U.S.C. § 103(a). Therefore the subject matter in the present invention is patentable over the teachings of Nellhaus, Versachuur, Sullivan, Johnson and/or Krubert.

C. Fees

No further fees are believed to be due. If, on the other hand, it is determined that further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

D. Conclusion

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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